

_____ National Birth Defects Prevention Study
INTRODUCTORY BUCCAL STUDY SCRIPT
(Read at End of CATI, Only for _____ Study)

As you read in the advance letter, there are two parts to the study. You just completed the first part, the interview, that will help us understand the environmental causes of birth defects. The second part of the study will help us understand the genetics of birth defects. We will mail a kit to you with small, soft brushes to collect cell samples from the inside of the mouth for yourself, your child, and your child's father. We will enclose \$20.00 per family in the kit to provide for any inconvenience. You can decide whether to take part in the second part of the study after you receive the kit. If you decide to participate, we will send an additional \$20 money order after you return the cheek cell samples to compensate you for the time required to complete the entire study. I would like to verify your current mailing address. Do you still receive mail at the same address to which we sent your advance letter? (What is your current address?)

USE FOLLOWING FOR NOTES. THEN, RECORD UPDATE INFORMATION IN TRACKING SYSTEM. NOTE IN COMMENTS IF MOM AND DAD LIVE SEPARATELY.

CORRECTED ADDRESS—MOTHER :

STREET: _____
APARTMENT: _____
CITY: _____
STATE: _____ ZIPCODE: _____

CORRECTED ADDRESS—FATHER (IF DIFFERENT FROM MOTHER):

STREET: _____
APARTMENT: _____
CITY: _____
STATE: _____ ZIPCODE: _____

CHILD LIVES WITH:

BOTH PARENTS____ MOTHER ONLY____ FATHER ONLY____
OTHER (SPECIFY): _____

CORRECTED ADDRESS—CHILD (IF DIFFERENT FROM PARENTS):

STREET: _____
APARTMENT: _____
CITY: _____
STATE: _____ ZIPCODE: _____

____ **MOTHER REFUSED ENTIRE KIT; REQUESTED DO NOT SEND KIT.**

REASON: _____

____ **MOTHER REFUSED PART OF KIT; DO NOT SEND KIT TO:**

MOTHER ____ CHILD ____ FATHER ____

REASON: _____

IF MOTHER ASKS QUESTIONS ABOUT THE BUCCAL STUDY, SAY:

I'd be happy to answer any of your questions now, but you might find it more helpful if you wait to see the kit. The kit comes with specific instructions and explains this part of the study, including confidentiality of the samples.

ANSWER QUESTIONS:

PROCEDURES: Samples are collected by brushing the inside of the cheek (mouth) with a soft brush for 30 seconds. (The brush is like a very small toothbrush.) These samples will be used to study genes, which may play a role in why some babies have birth defects. They will only be used to study birth defects and for no other purpose. We have no plans to ever destroy these samples.

RISKS: The possible physical risk of this procedure is for temporary, minor discomfort to the inside of the mouth. To protect your confidentiality, no names or other personal information will be attached to the samples.

BENEFITS: There is no personal benefit to you for taking part in this study. The major benefit is that this study may result in a better understanding of the causes of birth defects. This information will be helpful to all individuals of childbearing age, or who may have children someday. We will share what we learn with other health professionals through medical publications. None of these publications will include information, which could identify you or your child in any way.

CONFIDENTIALITY: All information that we gather in this study will be kept private. This is assured under Section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)). The Certificate of Confidentiality prevents study staff from being forced under a court order or other legal action to identify you or anyone else in this study. Records may be reviewed by officials checking on the quality of the research. This protection lasts forever (even after death) for any persons who were subjects in the research during any time the certificate was in effect. Cheek cell samples will be stored without your names but are linkable. Information about you may be shared with other participating sites and other researchers when and if it has been approved by research review committees. The shared data will not contain any information that could identify any individual. This information will be used only for the study of birth defects. If you would like a copy of the Certificate of Confidentiality for this project, please call Ms. _____ or Ms. _____ at _____ and it will be provided to you.

COSTS/COMPENSATION: Parents who agree to provide cheek cell samples on themselves and their child will receive \$20.00 per family with the kit to provide for any expense or inconvenience. We will also send an additional \$20 money order after you return the cheek cell samples to compensate you for the time required to complete the entire study. There is no payment for medical treatment in the unlikely event of injury as a result of taking part in this study. **(IF MOTHER AND FATHER LIVE**

SEPARATELY: Separate kits can be mailed to the mother and father of the child. We will enclose \$10.00 in each of those kits.) We will also send an additional \$10 money order to each parent that returns the cheek cell samples to compensate them for the time required to complete the entire study.

RIGHT TO REFUSE OR WITHDRAW: Participation in all parts of this study is voluntary. You and your child are free to not take part in the study and you are free to withdraw from any or all parts of this study at any time without penalty or loss of benefits to you. If at any time in the future, you would like to have your interview information or cheek cell samples destroyed or removed from the study, please call Ms. _____ or Ms. _____ at _____.

CONTROL and OWNERSHIP OF BIOLOGIC MATERIALS: Some of the cheek cell samples will be studied shortly after they are collected. Most of the cheek cell samples will be stored in a specimen bank for studies in the future. Study researchers will have control over the stored samples unless you request that your sample be removed from storage. If you wish to have your specimen(s) removed from storage, please contact Ms. _____ at _____.

COMMERCIAL VALUE OF BIOLOGIC MATERIALS: We will not use the cheek cell samples collected from you for commercial purposes.

LABORATORY RESULTS:

The studies that will be done on these samples are not meant to test the medical status of you or your child. Since all studies will be done in research labs, we do not plan to return to you the results of the studies. Research labs do not have the same quality control standards as clinical labs. Research labs may also use less expensive techniques, which can make the tests less reliable than those from a clinical lab. However, a few of these studies may have clinical importance. For any tests that have clinical importance, we will publish summarized results in the study newsletter. This newsletter is sent to all participants. You will be able to request your test results that may have clinical importance from your study center. Each parent may request results for the child and for herself or himself. One parent may not request results for the other. If you have questions about whether any genetic tests would be useful to you, we recommend that you consult your health care provider.

CONTACTS: If you have any questions, please contact:

If you have questions about genetic testing or counseling, you may call:

_____.

If you have questions about your rights as a subject in this research study, please call 1-800/584-8814, leave a message including your name and phone number, and someone will call you back as soon as possible.

If you have specific questions about how to use the kit or collect the cheek samples, contact: